

Guide to Fees for Scientific Animal Protection

INTRODUCTION

The Health Products Regulatory Authority (HPRA) is the competent authority for the protection of animals used for scientific purposes under S.I. No. 543 of 2012. This guide is intended to assist applicants in identifying the correct category of fee to accompany applications for authorisation. It follows the order of the fees in the 'Fee Application Form (Scientific Animal Protection)' and uses the fee code numbers in that form. The fee application form should be completed and submitted with all applications.

Applications submitted without the correct fee will not be validated by the HPRA and cannot therefore be evaluated.

1 INDIVIDUAL AUTHORISATION FEES

1.1 Application fees

Code **810** applies to individuals applying for a new authorisation, reactivating their existing authorisation, or re-applying for an authorisation that has expired or is due to expire within 28 days. Payment is due with the relevant application for authorisation.

1.2 Annual fee

Code **811** is an annual fee payable in respect of each individual authorisation. This fee applies to all individuals including technicians carrying out procedures or euthanasia of animals, as well as researchers, project managers, etc.

An invoice is issued annually to each establishment based on the number of authorised individuals in the establishment. Where an individual has two or more authorisations in respect of more than one establishment, the annual fee will be payable for each authorisation.

An individual who has paid an application fee for authorisation in the current calendar year, and authorisations that are inactivated before 01 July each year, will not be charged an annual fee for that year. Authorisations inactivated on 01 July and after that date will be charged a full year's fee.

Annual fees must not be paid in advance of annual invoices being issued by the HPRA in July.

1.3 Short-term individual authorisation for a period of two months or less

Code **812** is a reduced fee which applies to a once-off short-term individual authorisation, for example, for the purposes of demonstrating a procedure or for training in a procedure, where the authorisations are for a period of two months or less.

2 BREEDER/SUPPLIER/USER AUTHORISATION FEES (ESTABLISHMENT)

Fee codes **830-838** are annual fees payable for each establishment based on the number of individual authorisations in place at the establishment.

Breeder/Supplier/User authorisation fees must not be paid in advance of the annual invoices issued by the HPRA in October.

3 INSPECTION FEES

Codes **820** and **821** apply to fees for inspections conducted in response to suspected non-compliance, e.g. follow-up inspections, for cause inspections.

An inspection fee per day/hour per member of the inspection team is payable in relation to each inspection of each site. Travel expenses will also apply to follow-up inspections.

No fees will apply to routine and compliance inspections.

4 PROJECT FEES

Code **804** is a once-off fee and applies to research projects of whatever nature that are submitted without ethical approval.

Code **805** applies to 'fast-track applications' where an authorisation is sought within 21 working days from the date of validation. All other applications will be considered within the designated 40 or 55 working day time frame, in accordance with legislative obligations.

Code **806** applies to 'fast-track' evaluation of project amendment applications where the evaluation is sought within 21 working days from the date of validation. All other applications for project amendments will be considered within the designated 40 working day time frame.

HPRA
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